Trends In Amplification

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The SOUNDTEC Direct System

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While conventional amplification provides significant help to millions of hearing impaired individuals suffering from the "silent hurt", many of those who could benefit from hearing aids do not seek this treatment. The SOUNDTEC Direct System, a partially implanted middle ear hearing system, has been developed as an alternative treatment for moderate-to-severe sensorineural hearing loss. The Direct System was designed in an attempt to overcome some of the limitations of conventional amplification, such as feedback, occlusion, and distortion. The Direct System is the first FDA-approved middle ear implant that has a minimally invasive transcanal surgical approach.

Results of a 103-patient multi-site clinical trial comparing averaged performance of the Direct System condition to the preimplant hearing aid condition, show statistically significant improvement for functional gain measures, high-frequency amplification, speech recognition scores in quiet, perceived aided benefit, sound quality perception, and satisfaction. Additionally, the perceptions of feedback and occlusion were reduced or eliminated with the Direct System compared to the preimplant hearing aid condition.

Device Description

The Direct System is an electromagnetic, partially implanted, middle ear hearing device. The system consists of the magnetic implant, a behind-the-ear (BTE) sound processor, and an earmold/coil assembly (ECA). The implant portion is a permanent rare-earth magnet sealed in a titanium canister. The sound processor, an analog 2-channel wide dynamic range compression (WDRC) circuit, attaches to the ECA that contains the electromagnetic coil. Refer to the illustration in Figure 1.

Principles of Operation

The sound processor converts sound energy into electrical signals, which are sent to the coil in the ECA. The coil transforms the electrical energy into an electromagnetic field that envelopes the implant, thus stimulating movement of the ossicular chain.

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This paper has not been presented orally. Some of the data presented in the paper has been given orally at AAA 2001.

Figure 1. Orientation of components.

Timeline

The SOUNDTEC Direct System is indicated for use in adults 18 years of age or older who desire an alternative to an acoustic hearing aid. Once candidacy is determined, the simple surgical technique of the transcanal approach takes about 30 minutes and generally is done with a local anesthetic. This makes it possible to perform the implantation in an office procedure room. The joint of the incus and the stapes is incised, the attachment ring of the implants placed around the head of the stapes, and the incudostapedial joint is allowed to return to its normal position.

Bench testing indicated the head of the stapes was the ideal place for attachment from both anatomic and physiologic considerations (Hough *et al.,* 2001). Following a 10-week healing period, the patient is fit with the sound processor and returns for adjustments and follow-up as needed.

Study Design

The study was conducted as a multicenter prospective trial comparing subjects' aided preimplant hearing aid to the Direct System (made at approximately 20 weeks postimplantation). Those subjects who fit the eligibility criteria and had consented to participate in the study were consecutively entered into the study. Analysis and statistical comparisons of outcomes between the preimplant hearing aid condition and the 20 weeks Direct System condition were used as the basis for determining safety and efficacy of the device compared to the subjects' hearing aid. The following data were submitted in our premarket application to the FDA in April, 2001.

Inclusion/Exclusion Criteria

Inclusion criteria included: Bilateral symmetrical sensorineural hearing loss, conformance with the audiometric threshold template (refer to Table 1), speech recognition scores of 60% or greater for NU-6 (Raffin andThornton, 1980), age of 21 to 80 years, ear canal of adequate size, dissatisfied hearing aid user, and the personal hearing aid's insertion gain matching NAL-R criteria as follows:

Pass criteria of subjects' hearing aid frequency response are ± 5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz for NAL-R target (Byrne *et al.,* 1986; Bentler *et al.,* 1993; Humes *et al.,* 1997).

Exclusion criteria included malformation of the external and/or middle ear, perforated tympanic membrane, acute otitis media, conductive hearing loss, disabling tinnitus, and retrocochlear hearing loss.

Performance Evaluation

Subjects were tested to find hearing thresholds, sound field thresholds, speech scores in quiet and noise, perceived aided benefit, and subjective perceptions. The performance of the Direct System was compared to the preimplant hearing aid condition for the ear to be implanted.

The subject was seated 1 meter from the speaker with a 0° azimuth. Aided and unaided

Table 1. Patient Selection

Air Conduction Thresholds							
Freq. (kHz)	0.25	0.5	1	2	3	4	6
Lower limit	0	0	10	35	50	50	40
Upper limit	50	60	70	75	75	80	100

warble tone thresholds were obtained for 250 to 6000 Hz in 2 dB step increments. Additionally, NU-6 (50-item) word lists and the Speech Perception in Noise Test (SPIN) (Kalikow *et al.,* 1977) were presented at 63 dB SPL. A +8 dB signal-to-noise ratio was used for the SPIN. The Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox, R, 1997) and the Hough Ear Institute Profile (HEIP) were administered. The APHAB was used to measure perceived aided benefit for the subscales of ease of communication (EC), reverberant noise (RN), and background noise (BN). Additionally, average scores for the three subscales were calculated. The HEIP is a validated questionnaire that evaluated satisfaction of the current hearing device, wearing time, tinnitus, masking effect with the current device, sound quality perceptions, presence of feedback and occlusion, and device preference.

Sound Processor and Earmold/Coil Assembly Fitting

The sound processor and ECA were fit to the subjects approximately 10 weeks after implantation. The settings of the sound processor and the fitting of the ECA were modified as needed for wearing comfort and optimal amplification during the acclimatization period. Three potentiometers were available for adjustment, including crossover frequency, low-frequency channel compression ratio, and compression kneepoint. Sites that showed the initial recommended potentiometer settings were provided fitting guides and troubleshooting suggestions for fine-tuning.

Demographic Summary

Most subjects in the study were male (66%). The average age was 65.1 years (median 67.0 years). The average duration of hearing loss was 15.4 ± 10.8 years. The right ear was chosen for implant in 60% of the cases. Nearly all of the subjects (85%) were binaural hearing aid users. In addition, the study subjects had been hearing aid users for an average of 7.1 years. The average time of use of the baseline hearing aid was 3.7 years. Circuit type of the hearing aids included 46% digital/programmable analog, 11% WDRC analog, 21% linear, 8% AGC analog, 8% unknown, and 6% true digital.

Primary Safety—Measures of Residual Hearing

For most subjects, the mass-loading effect of the device on averaged residual hearing was not clinically significant. Both air and bone conduction thresholds were measured preimplant and at 20 weeks postimplant. As seen in Figure 2, the average change in air conduction thresholds across the frequency range (250 to 8000 Hz) was 4.2 dB. The average change in bone conduction thresholds for 250 to 4000 Hz was 1.1 dB.

Safety—Adverse Events

No serious adverse event related to the device, such as death, severe loss of hearing or implant failure, was seen. Minor adverse events related to the device seen in the study included ear canal abrasion (3%), hematoma of ear canal or tympanic membrane (8%), tympanic membrane perforation (6%), imbalance/vertigo (2%), nausea/vomiting (1%), taste disturbance (3%), otitis media/externa (2%), tinnitus (1%), and electromagnetic interference (15%).

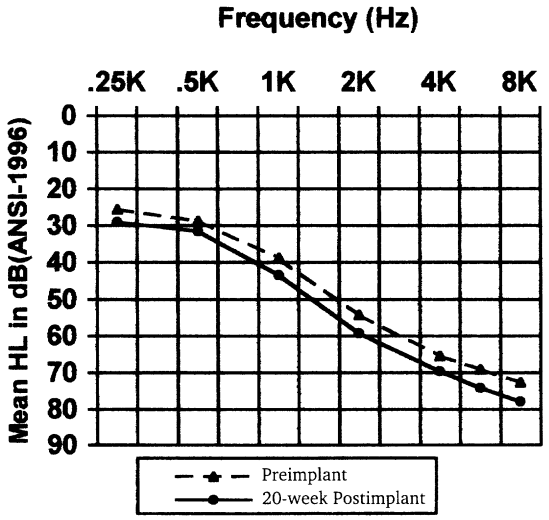

Figure 2. Residual hearing—air conduction thresholds.

Efficacy Outcomes

The study outcomes are listed below for the 95 subjects who had completed testing at the time of the premarket application submission. The Direct System condition demonstrated statistically significant increases for all items showing improvement.

- Increase in functional gain measures of 7.9dB for 500 to 4000 Hz and 9.6 dB for the high frequency average of 2000, 3000, and 4000 Hz. Refer to Figure 3.

  Additional functional gain is needed to compensate for the residual hearing threshold change. Aided thresholds are improved with the Direct System regardless of the decrease in residual hearing. Refer to Figure 4.

- A 5.3% increase in speech recognition scores in quiet (no difference was found for speech in noise). Speech in quiet was found to be statistically significant although clinical significance is questionable.

- Average improvement of 7.2 points for aided benefit as shown by the APHAB for the subscales of EC, BN, and RV. Refer to Figure 5. While the author of APHAB, Robyn Cox, suggests that an average change of 10 points or more for the three subscales is needed in general to show significant improvement between devices, the 7.2 points of improvement did prove to be statistically significant for this group (Cox, R, 1997).

- The Direct System was preferred by 99% of subjects as having the least amount of feedback as reported on the HEIP.

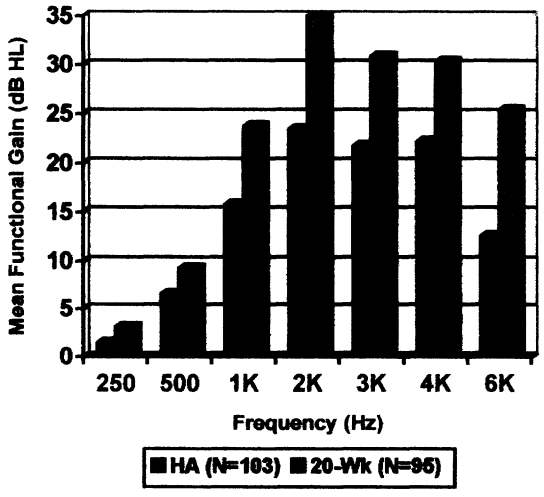

Figure 3. Functional gain for hearing aid and 20-week postimplant.

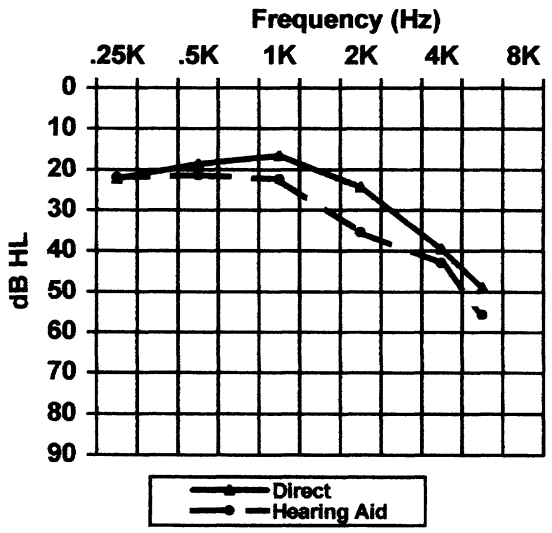

Figure 4. Aided thresholds in sound field.

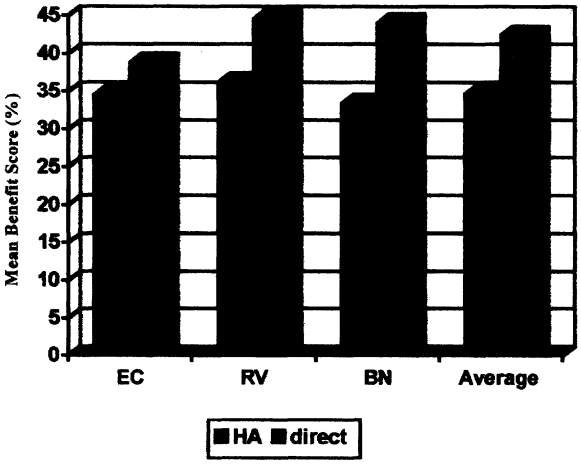

Figure 5. APHAB results.

- Subjects' perception of aided speech quality increased 27.8%. In the area of sound quality, 89% of subjects preferred the Direct System over their acoustic hearing aids.

- Occlusion with their acoustic hearing aids was reported by 54% of subjects; only 23% reported occlusion with the Direct System.

- Of 94 subjects responding, 89% preferred the Direct System in terms of overall satisfaction as reported on the HEIP.

The fact that speech in noise was not improved compared to performance with the preimplant hearing aid condition is most likely related to the monaural test condition. Since the poorer ear was implanted and tested monaurally in sound field, crucial phase and timing cues were not available to the listener. It is interesting to note the significant improvement in perception of aided benefit in background noise.

Looking Forward

Future developments include sound processor upgrades to an integrated processor and coil that fits in the ear and that eliminates the behind-the-ear component. Additionally, digital signal processing circuitry and multi-microphone technology are being evaluated for incorporation into the sound processor. These upgrades are external to the middle ear and do not require a surgical procedure. Additionally, a totally implantable system is being designed. The family of hearing products will continue to grow as new technology becomes available. Middle ear implants open the door to a new treatment option that should attract a greater number of hearing impaired individuals to seek help for the "silent hurt" with hearing aids as well as middle ear implants.

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